GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:58
ANSWERED ON:18.02.2009
CLINICAL TRIALS
Nikhil Kumar Shri ;Vijay Krishna Shri

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a)whether the Indian Council of Medical Research has recently drafted guidelines for compensation to participants for research related injury in the country;

(b) if so, the details thereof;

(c) whether the All India Institute of Medical Sciences has been doing clinical trials using stem cells as well and proposes to start a new batch of trials for the patients of Parkinsons disease shortly;

(d)if so, the details thereof; and

(e) the manner in which the Government proposes to protect the participants of clinical trials?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE(DR. ANBUMANI RAMADOSS)

(a)to(e): A statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 58 FOR 18TH FEBRUARY, 2009

(a) & (b): The Indian Council of Medical Research (ICMR), Forum for Ethical Review Committees in India (FERCI) and Indian Society of Clinical Research (ISCR) have issued draft Guidelines for Compensation to participants for Research Related Injury in India for comments. These guidelines are available on ICMR website www.icmr.nic.in. However, excerpts form the guidelines are annexed.

(c) & (d): AIIMS is doing clinical trial using Autologous Bone in India

(e) As per Schedule Y of Drugs and Cosmetics Act (Amended 2005), the Institutional Ethics Committee is responsible for protecting the rights, safety, well being of all trials subjects. As per Guidelines for Stem Cell Research and Therapy issued by Department of Biotechnolgoy & Indian Council of Medical Research (2007), all clinical trials with any stem cell shall have prior approval by Institutional Committee for Stem Cell Research & Therapy (ICSCRT), Institutional Ethics Committee (IEC) and Drugs ?Controller General of India (DCGI) for marketable product.